

# REPLACEMENT SHEET

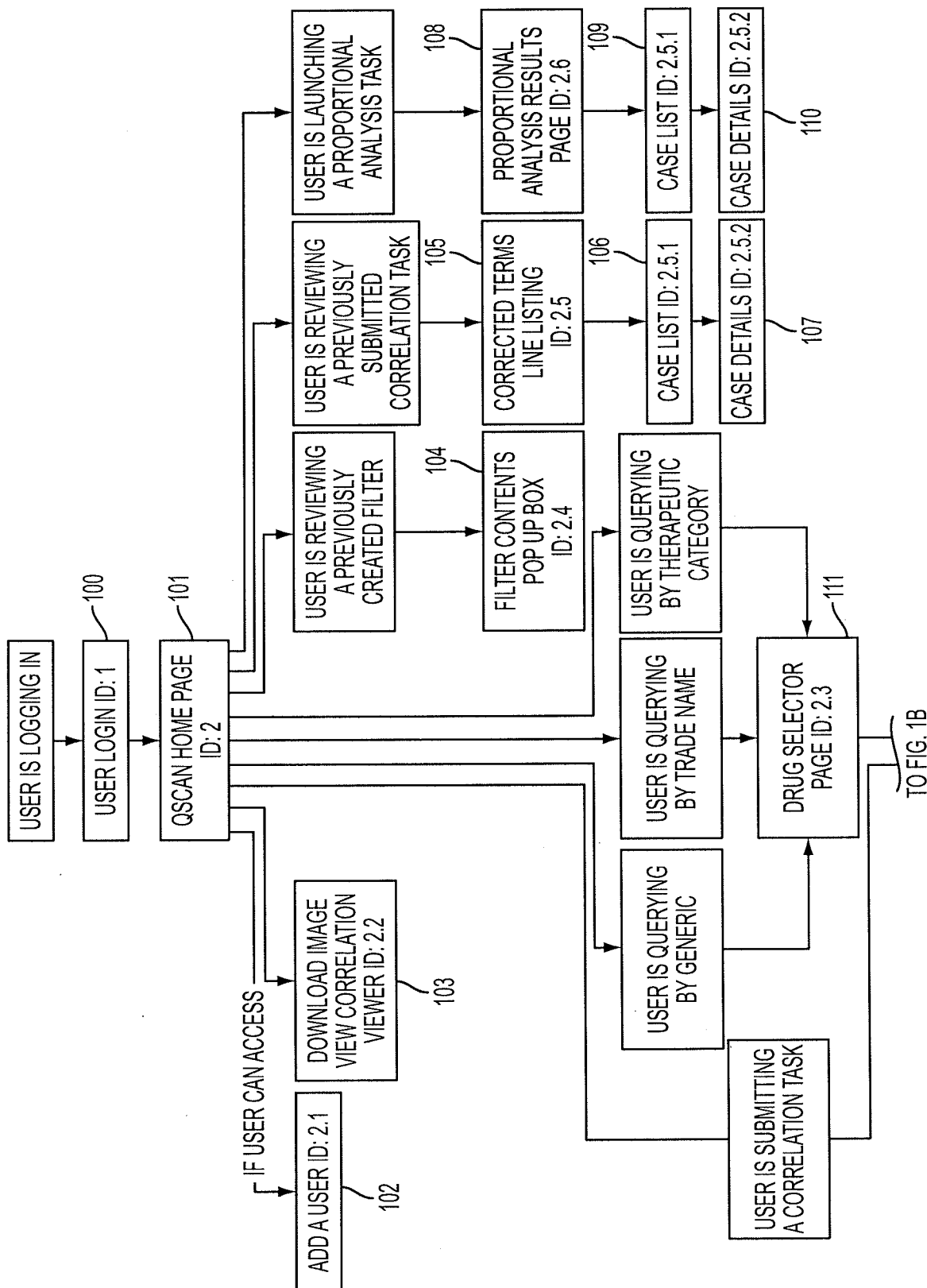


FIG. 1A

TO FIG. 1B

# REPLACEMENT SHEET

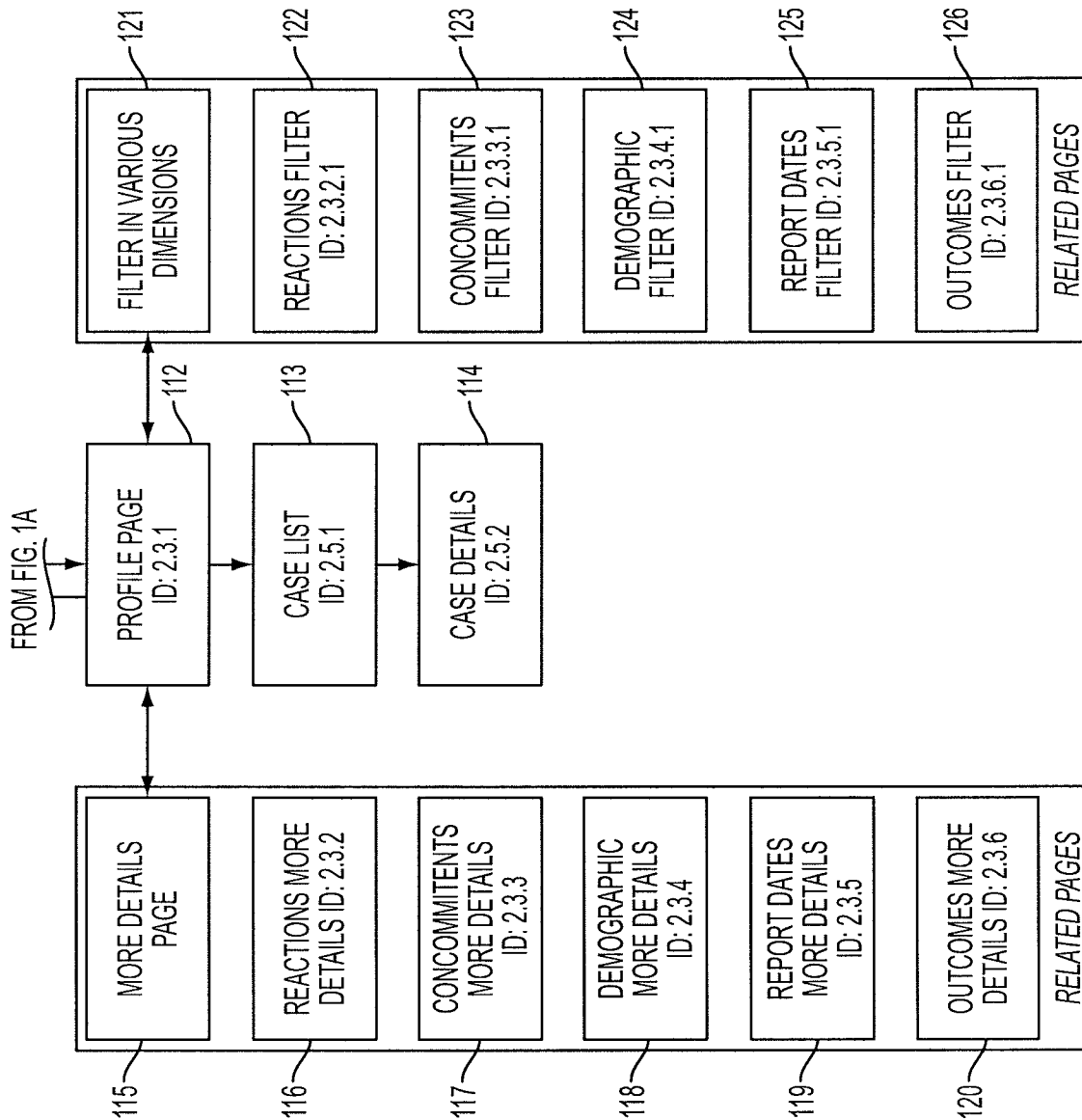


FIG. 1B

## REPLACEMENT SHEET

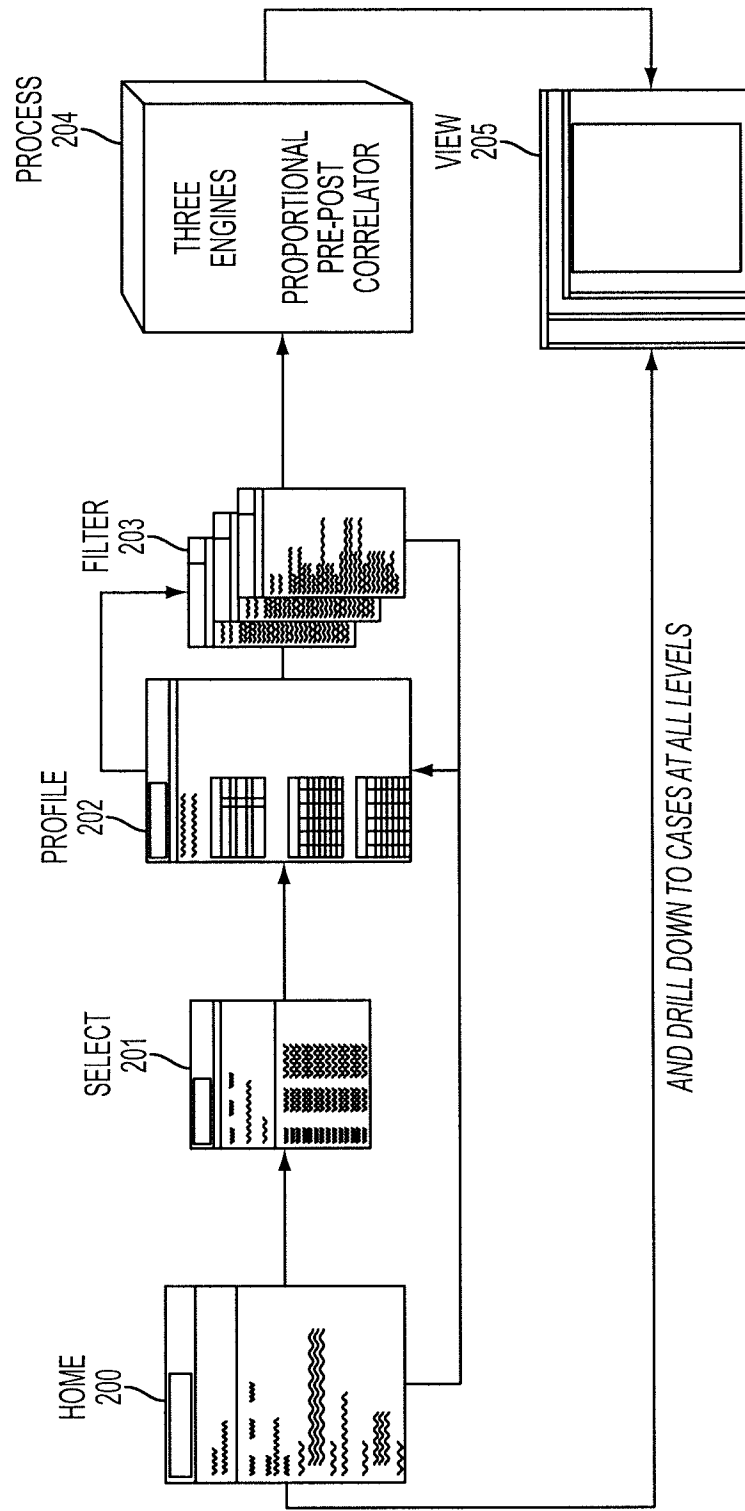


FIG. 2

## REPLACEMENT SHEET

**QSCAN Pharmacovigilance Selector/Profiler**

home

Selector/Profiler: Data source: FDA SRS/AERS, Combined Data

Generic Name: Trade Name: Therapeutic category:

Search Search Search

Filtering:

Saved filter: Select... View Apply

AEM Engine notices:

- [delete] [Dec. 22, 2000 6:41:42 PM] Completed correlation task #15 AMLODIPINE BESYLATE view results...
- [delete] [Dec. 22, 2000 6:25:17 PM] Completed correlation task #14 CANDESARTAN CILEXETIL view results...

Proportional analysis:

Compute for therapeutic category: Ace inhibitors

Go ☒ Bayesian filtering ☐ Compare only with therapeutic category

Administrative tasks:

- Add New User
- Log out
- Download the ImageView 1.1.4.1 Correlation viewer (1.3 MB)

FIG. 3

## REPLACEMENT SHEET

Filtering:  
Saved filter: Filter 2 View Apply

AEM Engine notices:  

- [delete] [Dec. 22, 2000 6:41:42 PM] Com
- [delete] [Dec. 22, 2000 6:25:17 PM] Com

Proportional analyses:  
Compute for therapeutic category: Ace Inhibit  
Go ☒ Bay

Filter Details: Microsoft ???

Current filter: Filter 2

400 Drug: CANDESARTAN CILEXETIL

Reactions:

80Cs: Included:

Concomitant Drugs: off

Demographics: Brackets:

Report Dates: off

Outcomes: Included

Close Window 404

FIG. 4

home > drug selector

500 Selector/Profiler: 501 Data source: FDA SRS/AERS Combined Data

Generic Name: Trade Name: Therapeutic category:

Search Search Search

502

Filtering:  
Saved filter: Select... View Apply

22 drugs in category: ACE INHIBITORS

| Generic Name:            | Trade Names: | Therapeutic Categories: | Pedigree |
|--------------------------|--------------|-------------------------|----------|
| AMILORIDE HYDROCHLORIDE  | AMILORIDE    | Ace Inhibitors          | ?        |
| AMLODIPINE BESYLATE      | AMIODIPINE   | Ace Inhibitors          | ?        |
| BENAZEPRIL HYDROCHLORIDE | BENAZEPRIL   | Ace Inhibitors          | ?        |
| CANDESARTAN CILEXETIL    | ATACAND      | Ace Inhibitors          | ?        |
| CAPTOPRIL                | ACE-HEMMER   | Ace Inhibitors          | ?        |
| ENALAPRIL MALEATE        | ACETENSIL    | Ace Inhibitors          | ?        |

FIG. 5

## REPLACEMENT SHEET

Merge Filter

✓ Reactions | Drugs | Outcomes | Report Sources | Timeframes | Demographics | Cases | Filter Notes |

deafness

Find Term

Reactions

☒

blood and lymphatic system disorders

☒

cardiac disorders

☒

congenital and familial/genetic disorders

☒

ear and labyrinth disorders

☒

external ear disorders (exc congenital)

☒

hearing disorders

☒

deafness and hyperacusis

☒

deafness conductive (exc otosclerosis)

☐

deafness neurosensory

☐

deafness permanent

☒

deafness transitory

☒

dysacusis

☒

hearing impaired

☐

hearing impairment aggravated

☐

hyperacusis

☒

hypoacusis

☐

presbycusis

☒

inner ear and vilith cranial nerve disorders

☒

middle ear disorders (exc congenital)

☒

miscellaneous ear disorders

☒

endocrine disorders

☒

eye disorders

☒

gastrointestinal disorders

Apply

Generate profile for this filter (This filter has not been profiled)

Save

FIG. 12

## REPLACEMENT SHEET

Below are the top 200 correlated terms for your analysis on CANDESARTAN CILEXETIL (Task 95) View with ImageView

| Correlated Terms |         |  |                |  |                |
|------------------|---------|--|----------------|--|----------------|
| [Rank]           | [Score] | [Term 1]                                     | [Category]     | [Term 2]   | [Category]     |
| 1                | 7706    | Female                                       | Sex            | CANDESARTAN CILEXETIL  | Target Drug    |
| 2                | 7661    | Renal Function Analysis                      | Other Reaction | Renal failure and impairment                                     | Other Reaction |
| 3                | 7244    | Paralysis (exc congenital and cranial nerve) | Other Reaction | Central nervous system hemorrhages and cerebrovascular accidents | Other Reaction |
| 4                | 6901    | HOS  | Outcome        | CANDESARTAN CILEXETIL  | Target Drug    |
| 5                | 6888    | TRIAMTERENE                                  | Other Drug     | DICLOFENAC SODIUM  | Other Drug     |
| 6                | 6286    | OTH  | Outcome        | CANDESARTAN CILEXETIL  | Target Drug    |
| 7                | 5868    | Sex Not Specified                            | Sex            | Age Not Specified  | Age            |
| 8                | 5773    | VERAPAMIL                                    | Other Drug     | TRIAMTERENE  | Other Drug     |
| 9                | 5765    | HOS  | Outcome        | Female   | Sex            |
| 10               | 5753    | Male   | Sex            | CANDESARTAN CILEXETIL  | Target Drug    |

FIG. 13

## REPLACEMENT SHEET

### Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Cases for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

Cases 1 to 18 of 18 cases

|   | 1401    | 1402 | 1403                      | 1404                    | 1405 | 1406   | 1407  | 1408    |
|---|---------|------|---------------------------|-------------------------|------|--|---|---------|
|   | Case ID | Sex  | Manufacturer Control Code | FDA Report Receipt Date | Age  | Drugs  | Reactions   | Serious |
| 1 | 3263641 | F    | 19990300088               | 1999-06-17              | 74   | Atacand  | Blood Creatinine Increased; Dialysis Nos; Renal Failure Aggravated  | N       |
| 2 | 3198047 | F    | 19990200143               | 1999-03-12              | 57   | Acuretic, Atrovastatin, Atacand, Cefixime, Nitro-Dur, Terbasmin Expectorante   | Blood Creatinine Increased; Blood Urea Increased; Hypotension NOS; Renal Failure Acute  | Y       |
| 3 | 3171644 | F    | 19981100002               | 1999-01-17              | 69   | Xanax, Acetylsalicylic Acid, Wellbutrin, Atacand, Arthrotec, Digoxin, Levaquin, Claritin, Antivert, Pyridium, Zolof, Dyazide, Verapamil-Slow Release, Ambien | Abdominal Pain Nos; Blood Creatinine Increased; Blood Urea Increased; Coronary Artery Disease Nos; Haemoptysis; Heart Rate Increased; Hypertension Aggravated; Renal Failure Acute  | N       |
| 4 | 3270258 | F    | 19990400499               | 1999-06-26              | 75   | Atacand, Hydrochlorothiazide   | Atrioventricular Blood Second Degree; Blood Creatinine Increased; Blood Pressure Decreased; Electrocardiogram St Segment Depression; Electrocardiogram U Wave Appearance; Electrolyte Imbalance Hypochloraemia; Hypokalaemia; Hyponatraemia; Loss of Consciousness Nec; Renal Impairment Nos; Syncope | N       |

FIG. 14



## REPLACEMENT SHEET

### Correlation Details

Analyzed Drug: CANDESARTAN CILEXETIL

Case for term pair: Renal function analyses [Other Reaction] / Renal failure and impairment [Other Reaction]

|      |                            |  |                            |                              |   |                             |
|------|----------------------------|--|----------------------------|------------------------------|---|-----------------------------|
| 1501 | Case ID:                   | 3198047  |                            |                              |   |                             |
| 1502 | Sex:                       | F  |                            |                              |   |                             |
| 1503 | Age:                       | 57.0 years, 0.0 months   |                            |                              |   |                             |
| 1504 | Reactions:                 | <b>As Reported</b>   | <b>Preferred Term</b>      | <b>High Level Term</b>       | <b>High Level Group Term</b>                                  | <b>System Organ Class</b>   |
|      |                            | Blood Creatinine Increased   | Blood Creatinine Increased | Renal Function analysis      | Renal and urinary tract investigations                        | Investigations              |
|      |                            | Blood Urea Increased   | Blood Urea Increased       | Renal Function analysis      | Renal and urinary tract investigations and urinalysis         | Investigations              |
|      |                            | Hypotension NOS  | Hypotension NOS            | Hypotension                  | Decreased and non-specific blood pressure disorders and shock | Vascular disorders          |
|      |                            | Renal Failure Acute  | Renal Failure Acute        | Renal failure and impairment | Renal disorders (exc nephropathies)                           | Renal and urinary disorders |
| 1505 | Concomitant Drugs:         | <b>Name</b>  | <b>Dose</b>                | <b>Route</b>                 | <b>Suspect</b>  | <b>Status</b>               |
|      |                            | Acuretic   | TAB QD                     |                              | Yes   |                             |
|      |                            | Atorvastatin   |                            |                              | No  |                             |
|      |                            | Atacand  | 16 MG QD PO ORAL           |                              | Yes   |                             |
|      |                            | Cefixime   |                            |                              | No  |                             |
|      |                            | Nitro-Dur  |                            |                              | No  |                             |
|      |                            | Terbasmin Expectorante   |                            |                              | No  |                             |
| 1506 | Outcomes:                  | HOSPITALIZATION-INITIAL OR PROLONGED (HO)<br>LIFE-THREATENING (LT) |                            |                              |   |                             |
| 1507 | Manufacturer Control Code: | 19990200143  |                            |                              |   |                             |
| 1508 | Manufacturer Date:         | 1999-03-5  |                            |                              |   |                             |
| 1509 | Adverse Event Date:        | 1998-12-13   |                            |                              |   |                             |
| 1510 | Report Type:               | EXP  |                            |                              |   |                             |
| 1511 | Report Source:             | OTH  |                            |                              |   |                             |
| 1512 | Case Source:               | AERS   |                            |                              |   |                             |
| 1513 | Narrative:                 |  |                            |                              |   |                             |

FIG. 15

## REPLACEMENT SHEET

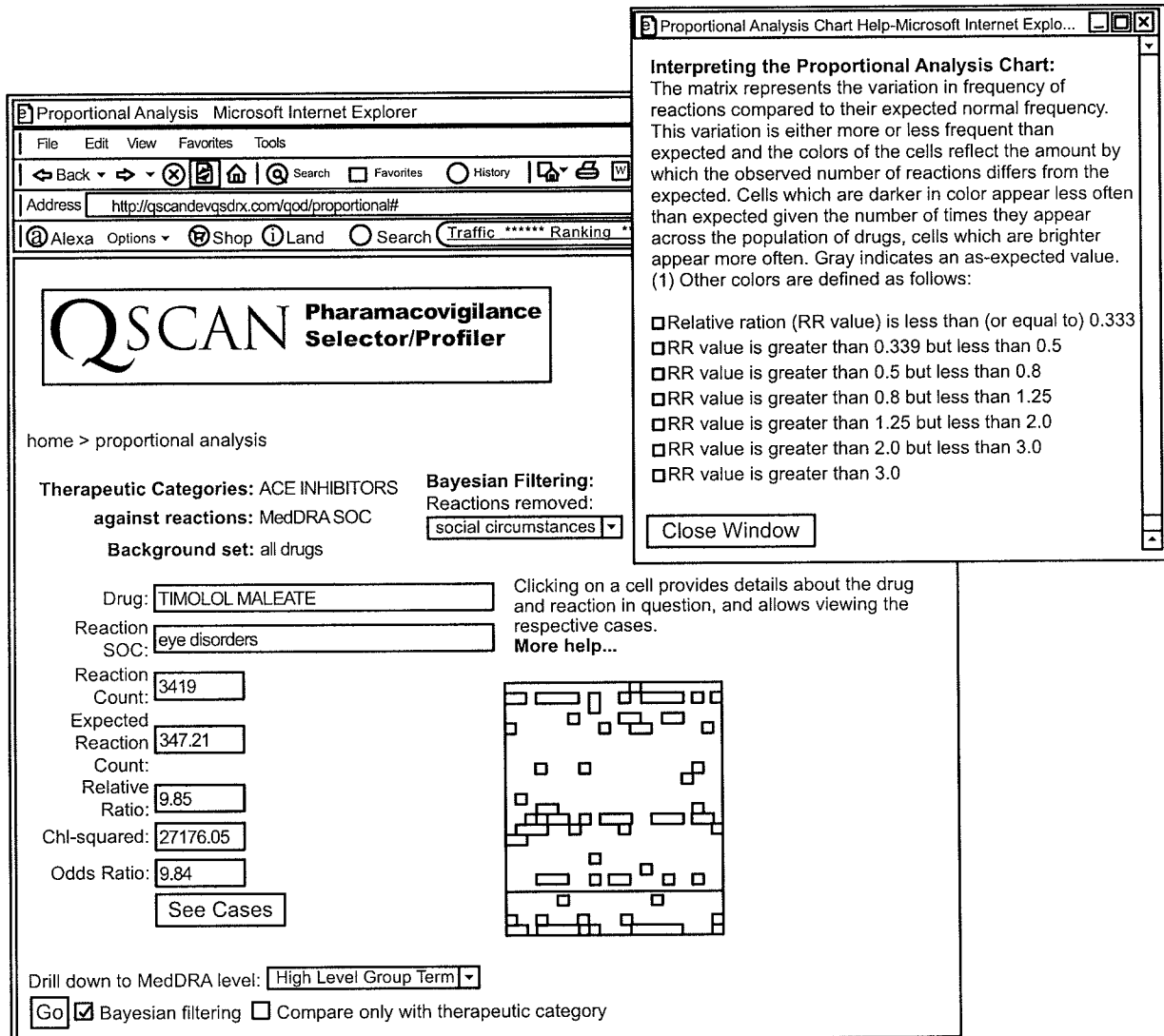


FIG. 17

## REPLACEMENT SHEET

**Proportional Analysis**  
 [ACE INHIBITORS] vs. Reactions (SOCs)  
 View by HLGs

1800 Drug:

1801 Reaction:

1802 Reaction Count:

1803 Expected Reaction Count:

1804 Relative Ratio:

FIG. 18

550 entries for this analysis are displayed below.

| Correlated Terms |  | 1900                       | 1901    | 1902             | 1903             | 1904 |
|------------------|--|----------------------------|---------|------------------|------------------|------|
|                  | [Reaction]   | [Drug]                     | [Count] | [Expected Count] | [Relative Ratio] |      |
| 1                | 6: Eye disorders   | 19: TIMOLOL MALEATE        | 3392    | 346.3            | 9.8              |      |
| 2                | 24: Surgical and medical procedures                                | 2: AMLODIPINE BESYLATE     | 1732    | 200.4            | 8.6              |      |
| 3                | 14: Metabolism and nutrition disorders                             | 1: AMILORIDE HYDROCHLORIDE | 838     | 266.5            | 3.1              |      |
| 4                | 24: Surgical and medical procedures                                | 13: METHYLDOPA             | 37      | 15.6             | 2.4              |      |
| 5                | 16: Neoplasms benign and malignant<br>(including cysts and polyps) | 17: RESERPINE              | 65      | 28.6             | 2.3              |      |
| 6                | 4: Ear and labyrinth disorders                                     | 4: CANDESARTAN CILEXETIL   | 32      | 14.3             | 2.2              |      |
| 7                | 24: Surgical and medical procedures                                | 20: TRANDOLAPRIL           | 13      | 6                | 2.2              |      |
| 8                | 14: Metabolism and nutrition disorders                             | 18: SPIRONOLACTONE         | 1330    | 616.1            | 2.2              |      |

FIG. 19

# REPLACEMENT SHEET

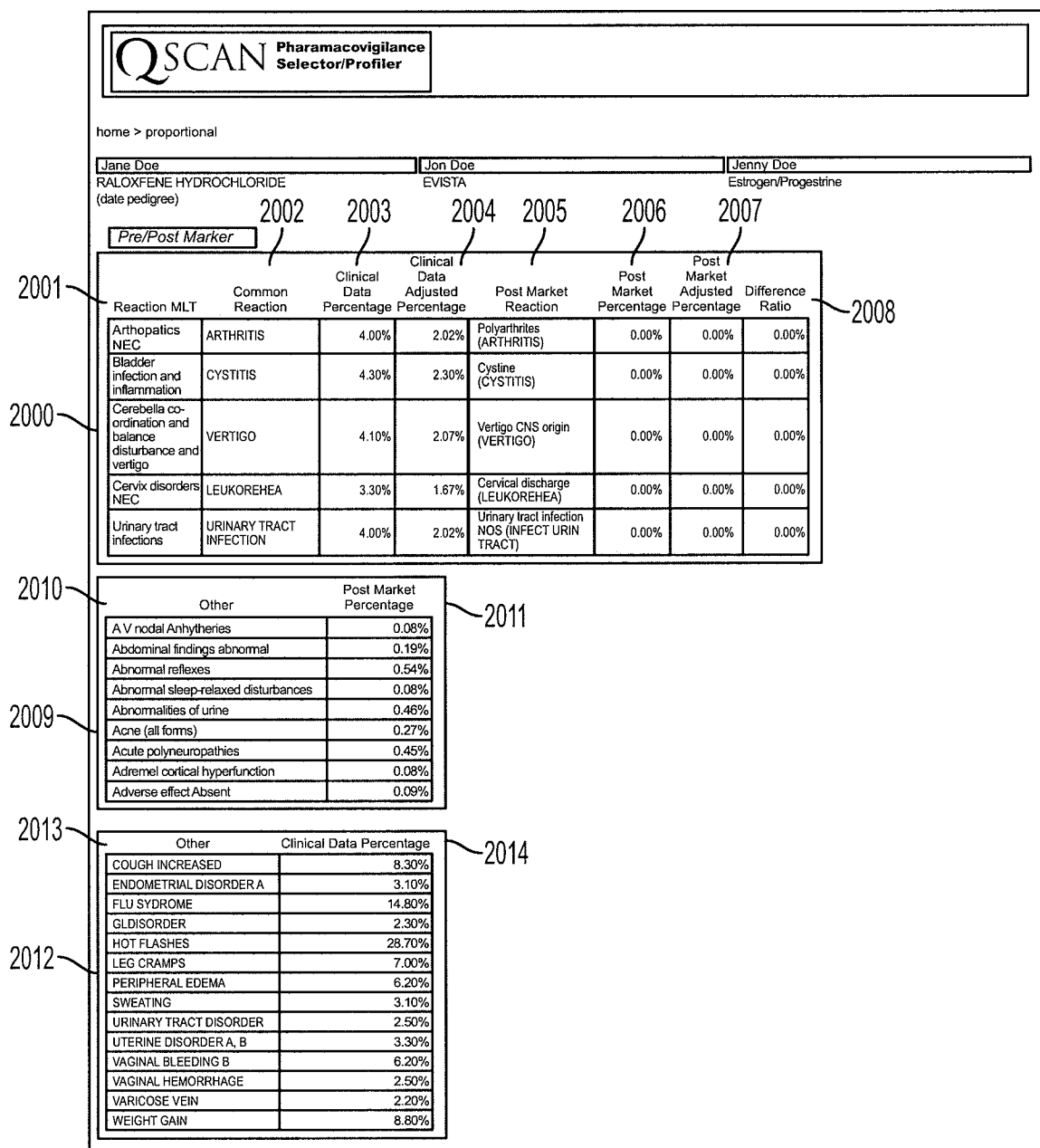


FIG. 20

# REPLACEMENT SHEET

home > drug selector > drug profile > case list

Drug: **BENAZEPRIL HYDROCHLORIDE**

Reactions: **SOCs:**

Concomitant Drugs: off

Demographics: off

Report Dates: off

Outcomes: off

Summary view... Cases 1 to 50 of 268 cases

6 pages:

1 51 101 151 201 251

|   | [Case ID] | [Sex] | [Manufacturer Control Code] | [FDA Report Receipt Date] | [Age] | Drugs   | Reactions   |      |   |
|---|-----------|-------|-----------------------------|---------------------------|-------|---|---|------|---|
|   | 2100      | 2101  | 2102                        | 2103                      | 2104  | 2105  | 2106  | 2107 |   |
| 1 | 3510123   | F     | 200010174BBE                | 2000-06-1                 |       | Tylenol, Albuterol, Duraluss G Pm, Aspirin, Asulfamethoxzo Ex Bid, Astelin, Lotansin, Zyrtec, Dolebrex, Benadryl, Premarin, Lasix, Hclz 25 Mg, Hydrocodone, Immune Globulin Intravenous (Human), Gamimune N 10% - Placebo, Iodine, Xylocaine, Claritin, Glucophage, Methylprednisolone, Nasonex, Singulair, Prilosec, Oxygen, Paxil, Solumadrol Pack, Rezulin 200 Mg Am | Cardiac Murmur Nos; Dyspepsia; Dyspnosa Nos; Oedenia Lower Limb; Pain in Limb; Phlebitis Nos; Physical Examination Nos Abnormal; Rhinorrhosa; Tenderness Nos; Venous Thrombosis Deep Limb |      | Y |
| 2 | C01979033 | F     | 97USA10851                  | 1997-09-8                 |       | LOTENSIN  | Hypertension NOS, Tablet in stool   |      | N |
| 3 | 3204365   | F     | 98061673                    | 1998-08-26                |       | Aspirin Coated, Lotensin, Niaspan   | Asthenia, Dizziness (Exc Vertigo), Dyspepsia, Flushing, Pain Nos  |      | Y |
| 4 | C01455473 | F     | 933544001                   | 1994-05-28                |       | LOTENSIN  | Nausea, Vasodilatation  |      | N |

FIG. 21